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INVENTOR(S)

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TITLE OF THE INVENTION (500 characters max)

METHOD AND APPARATUS FOR AN IMPROVED ANALYTE SENSOR

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ENCLOSED APPLICATION PARTS (check all that apply)

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☑ Drawing(s) Number of Sheets 6
☐ Application Data Sheet. See 37 CFR 1.76
☐ CD(s), Number
☑ Other (specify) Application cover sheet; return postcard.

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☑ Applicant claims small entity status. See 37 CFR 1.27.
☐ A check or money order is enclosed to cover the filing fees
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Respectfully submitted,

SIGNATURE _____ Date 06/13/2003

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PROVISIONAL PATENT APPLICATION

METHOD AND APPARATUS FOR AN IMPROVED ANALYTE SENSOR

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METHOD AND APPARATUS FOR AN IMPROVED ANALYTE SENSOR

BACKGROUND OF THE INVENTION

Lancing devices are known in the medical health-care products industry for piercing the skin to produce blood for analysis. Typically, a drop of blood for this type of analysis is obtained by making a small incision in the fingertip, creating a small wound, which generates a small blood droplet on the surface of the skin.

Early methods of lancing included piercing or slicing the skin with a needle or razor. Current methods utilize lancing devices that contain a multitude of spring, cam and mass actuators to drive the lancet. These include cantilever springs, diaphragms, coil springs, as well as gravity plumbs used to drive the lancet. The device may be held against the skin and mechanically triggered to ballistically launch the lancet. Unfortunately, the pain associated with each lancing event using known technology discourages patients from testing. In addition to vibratory stimulation of the skin as the driver impacts the end of a launcher stop, known spring based devices have the possibility of firing lancets that harmonically oscillate against the patient tissue, causing multiple strikes due to recoil. This recoil and multiple strikes of the lancet is one major impediment to patient compliance with a structured glucose monitoring regime.

Success rate generally encompasses the probability of producing a blood sample with one lancing action, which is sufficient in volume to perform the desired analytical test. The blood may appear spontaneously at the surface of the skin, or may be "milked" from the wound. Milking generally involves pressing the side of the digit, or in proximity of the wound to express the blood to the surface. In traditional methods, the blood droplet produced by the lancing action must reach the surface of the skin to be viable for testing.

When using existing methods, blood often flows from the cut blood vessels but is then trapped below the surface of the skin, forming a hematoma. In other instances, a wound is created, but no blood flows from the wound. In either case, the lancing process cannot be combined with the sample acquisition and testing step. Spontaneous blood droplet generation with current mechanical launching system varies between launcher

types but on average it is about 50% of lancet strikes, which would be spontaneous. Otherwise milking is required to yield blood. Mechanical launchers are unlikely to provide the means for integrated sample acquisition and testing if one out of every two strikes does not yield a spontaneous blood sample.

Many diabetic patients (insulin dependent) are required to self-test for blood glucose levels five to six times daily. The large number of steps required in traditional methods of glucose testing ranging from lancing, to milking of blood, applying blood to the test strip, and getting the measurements from the test strip discourages many diabetic patients from testing their blood glucose levels as often as recommended. Tight control of plasma glucose through frequent testing is therefore mandatory for disease management. The pain associated with each lancing event further discourages patients from testing. Additionally, the wound channel left on the patient by known systems may also be of a size that discourages those who are active with their hands or who are worried about healing of those wound channels from testing their glucose levels.

Another problem frequently encountered by patients who must use lancing equipment to obtain and analyze blood samples is the amount of manual dexterity and hand-eye coordination required to properly operate the lancing and sample testing equipment due to retinopathies and neuropathies particularly, severe in elderly diabetic patients. For those patients, operating existing lancet and sample testing equipment can be a challenge. Once a blood droplet is created, that droplet must then be guided into a receiving channel of a small test strip or the like. If the sample placement on the strip is unsuccessful, repetition of the entire procedure including re-lancing the skin to obtain a new blood droplet is necessary.

Measurement of glucose concentration is commonly based on the use of an enzyme such as glucose oxidase or glucose dehydrogenase. In such sensing schemes, glucose (substrate) is turned over by an enzyme layer resulting in change in the concentration of another species such as oxygen or hydrogen ion. The change in concentration of these species can be converted into some charge based or optical change at a transducer interface (sensing region). Alternatively, if the enzyme is electrically coupled to an inert electrode, such a reaction results in a change in electron flow at constant applied potential. Both types of transduction mechanisms are widely used in glucose sensing. In the former type of transduction scheme, the reaction zone can be decoupled from the sensing region. Thus, the reaction of the enzyme with the substrate

can be brought about in one region and the concentration measurement can be done in another region. In the latter scheme, the enzymatic reaction has to occur in close proximity to the sensing region (electrode surface) for electrical coupling. Some devices may also include sensor for analyzing sample fluid. Unfortunately, the storage ability of these devices are limited due to the need for some of these elements to be stored in inert environments.

The current sensing technologies do not attempt the separate the reaction zone from the sensing region. One disadvantage of this approach is that the enzyme layer has to be placed in close proximity to the sensing element. This results in considerable difficulty in manufacturing and/or stabilizing the chemistries associated with enzymatic reaction and the transduction scheme. For example in the optical transduction schemes, an oxygen sensing layer such as a silicone rubber film doped with a flurophore, such as Ru Tris Diphenyl Phenanthroline, is coupled to the enzymatic layer containing glucose oxidase. The chemicals used in making these layers interfere with proper functioning of each other. There is often considerable reduction in the enzyme activity. The resultant sensors have limited dynamic range or limited shelf life or both.

SUMMARY OF THE INVENTION

The present invention provides solutions for at least some of the drawbacks discussed above. Specifically, some embodiments of the present invention provide an improved fluid sampling device. To improve shelf stable storage, devices and methods for decoupling enzyme layer from the sensing region may be provided. What is desired is a device and method that decouples the enzymatic reaction zone from the sensing region while providing appropriate contacting of the two with the sample to be analyzed. At least some of these and other objectives described herein will be met by embodiments of the present invention.

In one aspect of the present invention, the invention relates to using the electronic tissue penetration device to drive a penetrating member into tissue, causing two separated storage areas to be opened during actuation.

In one embodiment of the present invention, a method of body fluid sampling is provided. The method comprises moving a penetrating member at conforming to a selectable velocity profile or motion waveform; piercing a storage area having a sensing area; piercing another storage area having an enzyme area separate from the sensing area

prior to piercing; and causing fluid to first flow to the enzyme area and then to the sensing area. The method may further comprise storing said enzyme area in an inert environment different from an environment for the sensing area.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides a solution for body fluid sampling. Specifically, some embodiments of the present invention provides a method for improving spontaneous blood generation. The invention may use a high density penetrating member design. It may use penetrating members of smaller size, such as but not limited to diameter or length, than those of conventional penetrating members known in the art. The device may be used for multiple lancing events without having to remove a disposable from the device. The invention may provide improved sensing capabilities. At least some of these and other objectives described herein will be met by embodiments of the present invention.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed. It may be noted that, as used in the specification and the appended claims, the singular forms "a", "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a material" may include mixtures of materials, reference to "a chamber" may include multiple chambers, and the like. References cited herein are hereby incorporated by reference in their entirety, except to the extent that they conflict with teachings explicitly set forth in this specification.

In this specification and in the claims which follow, reference will be made to a number of terms which shall be defined to have the following meanings:

"Optional" or "optionally" means that the subsequently described circumstance may or may not occur, so that the description includes instances where the circumstance occurs and instances where it does not. For example, if a device optionally contains a feature for analyzing a blood sample, this means that the analysis feature may or may not be present, and, thus, the description includes structures wherein a device possesses the analysis feature and structures wherein the analysis feature is not present.

The present invention may be used with a variety of different penetrating member drivers. It is contemplated that these penetrating member drivers may be spring based, solenoid based, magnetic driver based, nanomuscle based, or based on any other mechanism useful in moving a penetrating member along a path into tissue. It should be noted that the present invention is not limited by the type of driver used with the penetrating member feed mechanism. One suitable penetrating member driver for use with the present invention is shown in Figure 1. This is an embodiment of a solenoid type electromagnetic driver that is capable of driving an iron core or slug mounted to the penetrating member assembly using a direct current (DC) power supply. The electromagnetic driver includes a driver coil pack that is divided into three separate coils along the path of the penetrating member, two end coils and a middle coil. Direct current is alternated to the coils to advance and retract the penetrating member. Although the driver coil pack is shown with three coils, any suitable number of coils may be used, for example, 4, 5, 6, 7 or more coils may be used.

Referring to the embodiment of Figure 1, the stationary iron housing 10 may contain the driver coil pack with a first coil 12 flanked by iron spacers 14 which concentrate the magnetic flux at the inner diameter creating magnetic poles. The inner insulating housing 16 isolates the penetrating member 18 and iron core 20 from the coils and provides a smooth, low friction guide surface. The penetrating member guide 22 further centers the penetrating member 18 and iron core 20. The penetrating member 18 is protracted and retracted by alternating the current between the first coil 12, the middle coil, and the third coil to attract the iron core 20. Reversing the coil sequence and attracting the core and penetrating member back into the housing retracts the penetrating member. The penetrating member guide 22 also serves as a stop for the iron core 20 mounted to the penetrating member 18.

As discussed above, tissue penetration devices which employ spring or cam driving methods have a symmetrical or nearly symmetrical actuation displacement and velocity profiles on the advancement and retraction of the penetrating member as shown in Figures 2 and 3. In most of the available lancet devices, once the launch is initiated, the stored energy determines the velocity profile until the energy is dissipated. Controlling impact, retraction velocity, and dwell time of the penetrating member within the tissue can be useful in order to achieve a high success rate while accommodating variations in skin properties and minimize pain. Advantages can be achieved by taking

into account of the fact that tissue dwell time is related to the amount of skin deformation as the penetrating member tries to puncture the surface of the skin and variance in skin deformation from patient to patient based on skin hydration.

In this embodiment, the ability to control velocity and depth of penetration may be achieved by use of a controllable force driver where feedback is an integral part of driver control. Such drivers can control either metal or polymeric penetrating members or any other type of tissue penetration element. The dynamic control of such a driver is illustrated in Figure. 2C which illustrates an embodiment of a controlled displacement profile and Figure 2D which illustrates an embodiment of a the controlled velocity profile. These are compared to Figures 2A and 2B, which illustrate embodiments of displacement and velocity profiles, respectively, of a harmonic spring/mass powered driver. Reduced pain can be achieved by using impact velocities of greater than about 2 m/s entry of a tissue penetrating element, such as a lancet, into tissue. Other suitable embodiments of the penetrating member driver are described in commonly assigned, copending U.S. Patent Application Ser. No. 10/127,395, (Attorney Docket No. 38187-2551) filed April 19, 2002 and previously incorporated herein.

Figure 3 illustrates the operation of a feedback loop using a processor 60. The processor 60 stores profiles 62 in non-volatile memory. A user inputs information 64 about the desired circumstances or parameters for a lancing event. The processor 60 selects a driver profile 62 from a set of alternative driver profiles that have been preprogrammed in the processor 60 based on typical or desired tissue penetration device performance determined through testing at the factory or as programmed in by the operator. The processor 60 may customize by either scaling or modifying the profile based on additional user input information 64. Once the processor has chosen and customized the profile, the processor 60 is ready to modulate the power from the power supply 66 to the penetrating member driver 68 through an amplifier 70. The processor 60 may measure the location of the penetrating member 72 using a position sensing mechanism 74 through an analog to digital converter 76 linear encoder or other such transducer. Examples of position sensing mechanisms have been described in the embodiments above and may be found in the specification for commonly assigned, copending U.S. Patent Application Ser. No. 10/127,395, (Attorney Docket No. 38187-2551) filed April 19, 2002 and previously incorporated herein. The processor 60 calculates the movement of the penetrating member by comparing the actual profile of the

penetrating member to the predetermined profile. The processor 60 modulates the power to the penetrating member driver 68 through a signal generator 78, which may control the amplifier 70 so that the actual velocity profile of the penetrating member does not exceed the predetermined profile by more than a preset error limit. The error limit is the accuracy in the control of the penetrating member.

After the lancing event, the processor 60 can allow the user to rank the results of the lancing event. The processor 60 stores these results and constructs a database 80 for the individual user. Using the database 79, the processor 60 calculates the profile traits such as degree of painlessness, success rate, and blood volume for various profiles 62 depending on user input information 64 to optimize the profile to the individual user for subsequent lancing cycles. These profile traits depend on the characteristic phases of penetrating member advancement and retraction. The processor 60 uses these calculations to optimize profiles 62 for each user. In addition to user input information 64, an internal clock allows storage in the database 79 of information such as the time of day to generate a time stamp for the lancing event and the time between lancing events to anticipate the user's diurnal needs. The database stores information and statistics for each user and each profile that particular user uses.

In addition to varying the profiles, the processor 60 can be used to calculate the appropriate penetrating member diameter and geometry suitable to realize the blood volume required by the user. For example, if the user requires about 1-5 microliter volume of blood, the processor 60 may select a 200 micron diameter penetrating member to achieve these results. For each class of lancet, both diameter and lancet tip geometry, is stored in the processor 60 to correspond with upper and lower limits of attainable blood volume based on the predetermined displacement and velocity profiles.

The lancing device is capable of prompting the user for information at the beginning and the end of the lancing event to more adequately suit the user. The goal is to either change to a different profile or modify an existing profile. Once the profile is set, the force driving the penetrating member is varied during advancement and retraction to follow the profile. The method of lancing using the lancing device comprises selecting a profile, lancing according to the selected profile, determining lancing profile traits for each characteristic phase of the lancing cycle, and optimizing profile traits for subsequent lancing events.

Figure 4 illustrates an embodiment of a tissue penetration device, more specifically, a lancing device 80 that includes a controllable driver 179 coupled to a tissue penetration element. The lancing device 80 has a proximal end 81 and a distal end 82. At the distal end 82 is the tissue penetration element in the form of a penetrating member 83, which is coupled to an elongate coupler shaft 84 by a drive coupler 85. The elongate coupler shaft 84 has a proximal end 86 and a distal end 87. A driver coil pack 88 is disposed about the elongate coupler shaft 84 proximal of the penetrating member 83. A position sensor 91 is disposed about a proximal portion 92 of the elongate coupler shaft 84 and an electrical conductor 94 electrically couples a processor 93 to the position sensor 91. The elongate coupler shaft 84 driven by the driver coil pack 88 controlled by the position sensor 91 and processor 93 form the controllable driver, specifically, a controllable electromagnetic driver.

Referring to Figure 5, the lancing device 80 can be seen in more detail, in partial longitudinal section. The penetrating member 83 has a proximal end 95 and a distal end 96 with a sharpened point at the distal end 96 of the penetrating member 83 and a drive head 98 disposed at the proximal end 95 of the penetrating member 83. A penetrating member shaft 201 is disposed between the drive head 98 and the sharpened point 97. The penetrating member shaft 201 may be comprised of stainless steel, or any other suitable material or alloy and have a transverse dimension of about 0.1 to about 0.4 mm. The penetrating member shaft may have a length of about 3 mm to about 50 mm, specifically, about 15 mm to about 20 mm. The drive head 98 of the penetrating member 83 is an enlarged portion having a transverse dimension greater than a transverse dimension of the penetrating member shaft 201 distal of the drive head 98. This configuration allows the drive head 98 to be mechanically captured by the drive coupler 85. The drive head 98 may have a transverse dimension of about 0.5 to about 2 mm.

A magnetic member 102 is secured to the elongate coupler shaft 84 proximal of the drive coupler 85 on a distal portion 203 of the elongate coupler shaft 84. The magnetic member 102 is a substantially cylindrical piece of magnetic material having an axial lumen 204 extending the length of the magnetic member 102. The magnetic member 102 has an outer transverse dimension that allows the magnetic member 102 to slide easily within an axial lumen 105 of a low friction, possibly lubricious, polymer guide tube 105' disposed within the driver coil pack 88. The magnetic member 102 may have an outer transverse dimension of about 1.0 to about 5.0 mm, specifically, about 2.3

to about 2.5 mm. The magnetic member 102 may have a length of about 3.0 to about 5.0 mm, specifically, about 4.7 to about 4.9 mm. The magnetic member 102 can be made from a variety of magnetic materials including ferrous metals such as ferrous steel, iron, ferrite, or the like. The magnetic member 102 may be secured to the distal portion 203 of the elongate coupler shaft 84 by a variety of methods including adhesive or epoxy bonding, welding, crimping or any other suitable method.

Proximal of the magnetic member 102, an optical encoder flag 206 is secured to the elongate coupler shaft 84. The optical encoder flag 206 is configured to move within a slot 107 in the position sensor 91. The slot 107 of the position sensor 91 is formed between a first body portion 108 and a second body portion 109 of the position sensor 91. The slot 107 may have separation width of about 1.5 to about 2.0 mm. The optical encoder flag 206 can have a length of about 14 to about 18 mm, a width of about 3 to about 5 mm and a thickness of about 0.04 to about 0.06 mm.

The optical encoder flag 206 interacts with various optical beams generated by LEDs disposed on or in the position sensor body portions 108 and 109 in a predetermined manner. The interaction of the optical beams generated by the LEDs of the position sensor 91 generates a signal that indicates the longitudinal position of the optical flag 206 relative to the position sensor 91 with a substantially high degree of resolution. The resolution of the position sensor 91 may be about 200 to about 400 cycles per inch, specifically, about 350 to about 370 cycles per inch. The position sensor 91 may have a speed response time (position/time resolution) of 0 to about 120,000 Hz, where one dark and light stripe of the flag constitutes one Hertz, or cycle per second. The position of the optical encoder flag 206 relative to the magnetic member 102, driver coil pack 88 and position sensor 91 is such that the optical encoder 91 can provide precise positional information about the penetrating member 83 over the entire length of the penetrating member's power stroke.

An optical encoder that is suitable for the position sensor 91 is a linear optical incremental encoder, model HEDS 9200, manufactured by Agilent Technologies. The model HEDS 9200 may have a length of about 20 to about 30 mm, a width of about 8 to about 12 mm, and a height of about 9 to about 11 mm. Although the position sensor 91 illustrated is a linear optical incremental encoder, other suitable position sensor embodiments could be used, provided they posses the requisite positional resolution and time response. The HEDS 9200 is a two channel device where the channels are 90

degrees out of phase with each other. This results in a resolution of four times the basic cycle of the flag. These quadrature outputs make it possible for the processor to determine the direction of penetrating member travel. Other suitable position sensors include capacitive encoders, analog reflective sensors, such as the reflective position sensor discussed above, and the like.

A coupler shaft guide 111 is disposed towards the proximal end 81 of the lancing device 80. The guide 111 has a guide lumen 112 disposed in the guide 111 to slidingly accept the proximal portion 92 of the elongate coupler shaft 84. The guide 111 keeps the elongate coupler shaft 84 centered horizontally and vertically in the slot 102 of the optical encoder 91.

In another aspect of the present invention, an improved analyte measurement storage device will be described. The current invention teaches devices and methods for isolating the enzymatic region from the sensing region in such a way that they can be fabricated and stored without interacting with each other during their pre-use phase. However the regions can be properly coupled during their use for proper functioning.

Referring now to Figure 6, a penetrating member 200 such as one driven by device as taught herein (though not limited in that manner) may be used to puncture a structure 202 containing an enzyme area 204 and a sensing area 206. Septums or seals 208, 210, 212 and may be used to keep these two areas separated prior to use. As a nonlimiting example, the area 204 may be stored in an inert gas (non oxygen) environment, while the area 206 is stored in a different environment. The flow of fluid 220 into the region may be due to gravity, capillary force, vacuum, or other technique. The flow allows the fluid to first gather material from the enzyme area 204 which may prepare the fluid for sensing the area 206. These sensing techniques may be used with optical sensor as known to those skilled in the art.

In one embodiment of this invention, the enzyme layer is deposited on the surface of a capillary region through which the sample to be analyzed flows to the sensing region where the transduction takes place. The coating can be placed on the wall of the capillary itself, or on the surface of any component of the device such as a lancet that comes in contact with the sample as it flows toward the sensing region. As the sample moves through this region it either dissolves the enzyme layer or extracts the enzyme into the sample. The rate of this enzyme uptake by the sample can be adjusted such that by the time sample reaches the sensing region the enzyme has adequately interacted with the

analyte to present appropriate sample for detection by the sensor. This can be achieved by adjusting one or more of the following factors: 1) the length of the coated region along the sample flow path, 2) thickness of the coating, 3) chemical composition of the coating, 4) porosity of the coating, 5) speed of the flow of the sample. These methods and means of achieving the appropriate enzyme uptake may be dependent upon the particular chemistry of enzyme and other reagents and would be readily determined by those familiar with the art of enzyme chemistry. These alternatives are included in this invention by reference.

In another embodiment of this invention, the sensing regions can be located along the flow path of the sample. In such a configuration, the enzyme layer is still coated on the walls along the flow path; the sample picks up different amount of the enzyme as it passes over each of the sensing regions. Thus the sensing region closest to the sample entry port has the least amount of enzyme and the one furthest along the flow path has the most amount of the enzyme. Such as scheme can be advantageously used where the amount of enzyme required for getting optimal sensor signal depends upon the (unknown) amount of the analyte in the sample. Since the analyte content is not known a priori, series of signals obtained from the sensing regions as a function of the amount of enzyme taken up by the sample can be evaluated and the optimal signal can be used for determining the analyte concentration.

Although these embodiments refer to the enzyme as an example of the chemical that is taken up by the sample for analysis, any other chemical species that is required to be dissolved in on contacted with the sample before analysis could be thus disposed using the teachings of this invention.

The current invention results in several advantages in the devices for analyte sensing and methods of manufacturing the same. Isolation of the enzyme from the sensing regions allows one to use different or incompatibles chemistries such as solvents for manufacturing and depositing the sensing layer and the enzyme layer.

An example is a glucose sensor based on sensing of oxygen depletion by the reaction of glucose with glucose oxidase. In this type of sensors, the oxygen sensor could be made of a silicone rubber layer containing an oxygen sensing fluorophore. The solvents required for depositing this layer are usually lipophilic and will readily reduce the activity of glucose oxidase. These solvents, even in minute quantities, can outgas from the layer and over time gradually deactivate the enzyme. Based on the teachings of this

invetion, the oxygen-sensing layer and the enzyme layer can be physically isolated from each other. Or, they can be fabricated separately and then assembled together after adequate out gassing of the harmful solvents etc. Alternatively, the two layers can be separated by a physical barrier such as septum during the pre-use storage of the device. At the time of analysis, the barrier can be broken by application of energy (thermal or electrical) or by impact of an object such as a lancet. Using such a barrier would enable one to store the layers in different atmospheres. For example, the enzyme could be stored in nitrogen atmosphere while the oxygen sensing layer could be stored in oxygen or another gas composition adequate for calibration at the time of use or stability during storage. If the oxygen sensor is stored in an oxygen rich atmosphere, the dissolved oxygen could act as a reagent for the glucose-GOD reaction. Such a scheme will provide a baseline for the oxygen consumed by the reaction of glucose that is not limited by the dissolved oxygen content of the sample.

While the invention has been described and illustrated with reference to certain particular embodiments thereof, those skilled in the art will appreciate that various adaptations, changes, modifications, substitutions, deletions, or additions of procedures and protocols may be made without departing from the spirit and scope of the invention. For example, with any of the above embodiments, the location of the penetrating member drive device may be varied, relative to the penetrating members or the cartridge. With any of the above embodiments, the penetrating member tips may be uncovered during actuation (i.e. penetrating members do not pierce the penetrating member enclosure or protective foil during launch). With any of the above embodiments, the penetrating members may be a bare penetrating member during launch. With any of the above embodiments, the penetrating members may be bare penetrating members prior to launch as this may allow for significantly tighter densities of penetrating members. In some embodiments, the penetrating members may be bent, curved, textured, shaped, or otherwise treated at a proximal end or area to facilitate handling by an actuator. The penetrating member may be configured to have a notch or groove to facilitate coupling to a gripper. The notch or groove may be formed along an elongate portion of the penetrating member. With any of the above embodiments, the cavity may be on the bottom or the top of the cartridge, with the gripper on the other side. In some embodiments, analyte detecting members may be printed on the top, bottom, or side of the cavities. The front end of the cartridge maybe in contact with a user during lancing.

The same driver may be used for advancing and retraction of the penetrating member. The penetrating member may have a diameters and length suitable for obtaining the blood volumes described herein. The penetrating member driver may also be in substantially the same plane as the cartridge. The driver may use a through hole or other opening to engage a proximal end of a penetrating member to actuate the penetrating member along a path into and out of the tissue. The embodiments herein are adapted for use with lancing devices described in U.S. Patent Applications Ser. No. _____ Attorney Docket No. 38187-2551US and 38187-2606.

Expected variations or differences in the results are contemplated in accordance with the objects and practices of the present invention. It is intended, therefore, that the invention be defined by the scope of the claims which follow and that such claims be interpreted as broadly as is reasonable.

WHAT IS CLAIMED IS:

1. A method of body fluid sampling comprising:

moving a penetrating member at conforming to a selectable velocity profile or motion waveform;

piercing a storage area having a sensing area;

piercing another storage area having an enzyme area separate from the sensing area prior to piercing;

causing fluid to first flow to the enzyme area and then to the sensing area.

2. The device of claim 1 further comprising storing said enzyme area in an inert environment different from an environment for the sensing area.

3. A device for body fluid sampling usable with a cartridge housing a plurality of penetrating members, the device comprising:

a housing;

a penetrating member driver coupled to said housing and for use with said cartridge;

a processor for controlling said penetrating member driver to move at least one of said penetrating members at velocities which conform with a selectable velocity profile;

a storage area having a sensing area;

another storage area having an enzyme area separate from the sensing area prior to piercing;

wherein said penetrating member pierces opens both storage areas upon member actuation and causing body fluid to first flow to the enzyme area and then to the sensing area.

ABSTRACT OF THE DISCLOSURE

A method of body fluid sampling is provided. The method comprises moving a penetrating member at conforming to a selectable velocity profile or motion waveform; piercing a storage area having a sensing area; piercing another storage area having an enzyme area separate from the sensing area prior to piercing; and causing fluid to first flow to the enzyme area and then to the sensing area. The method may further comprise storing said enzyme area in an inert environment different from an environment for the sensing area.

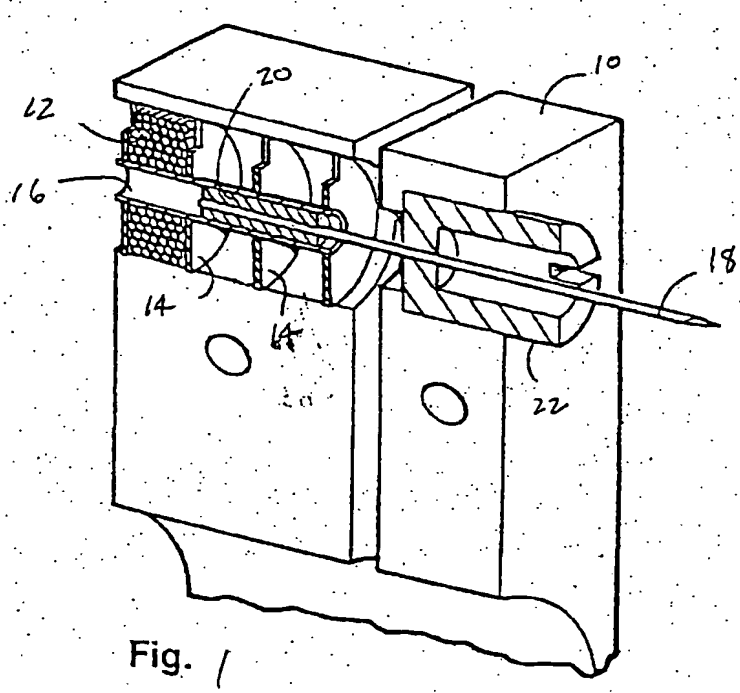

Fig. 1

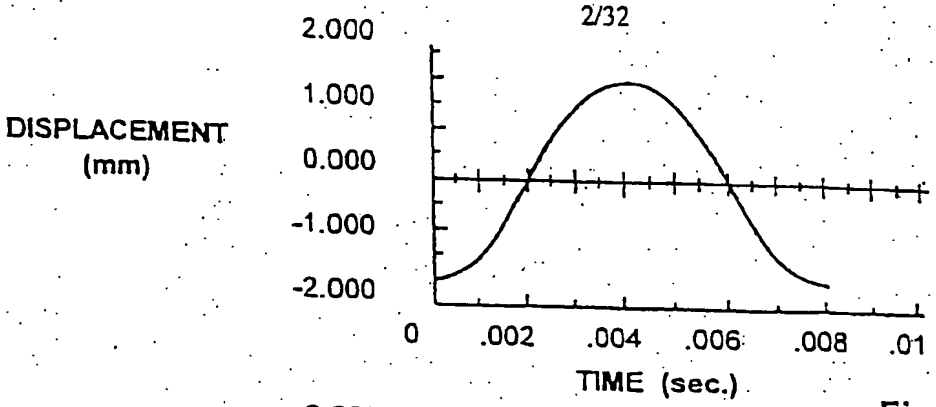

Fig. 2A

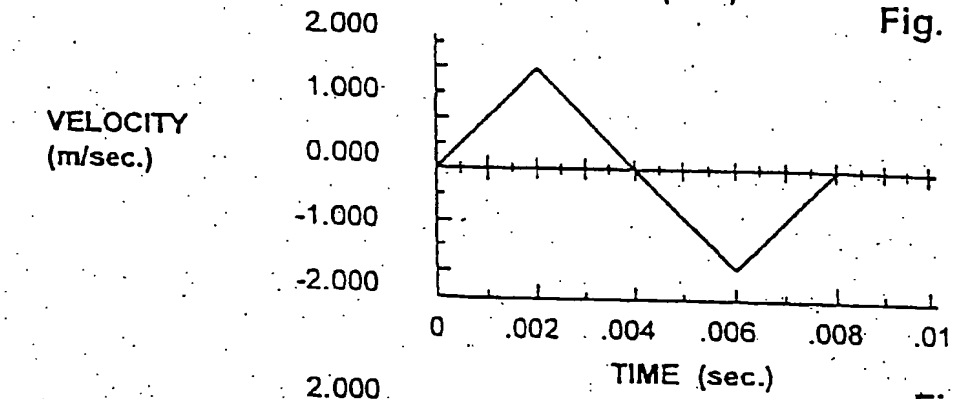

Fig. 2B

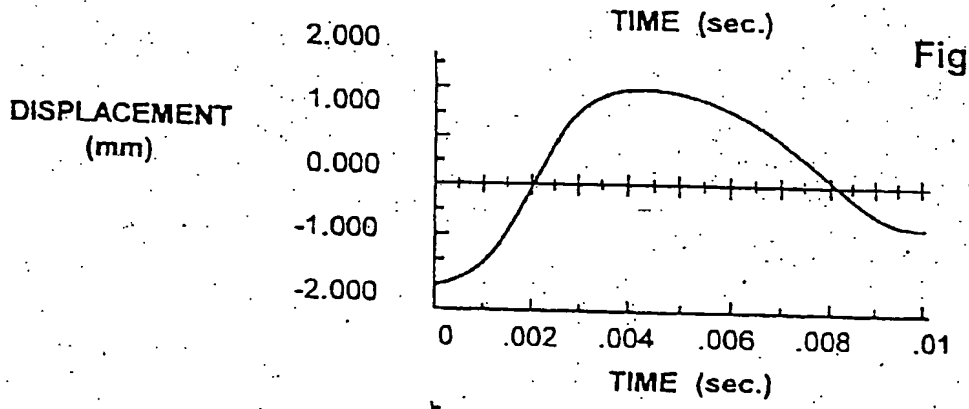

Fig. 2C

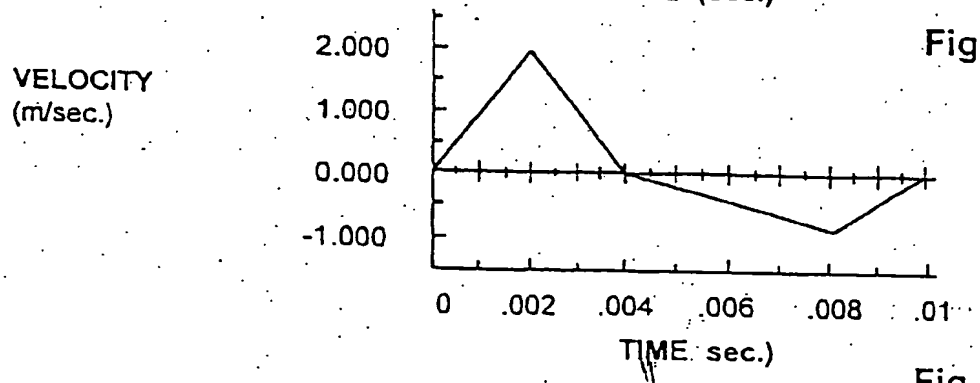

Fig. 2D

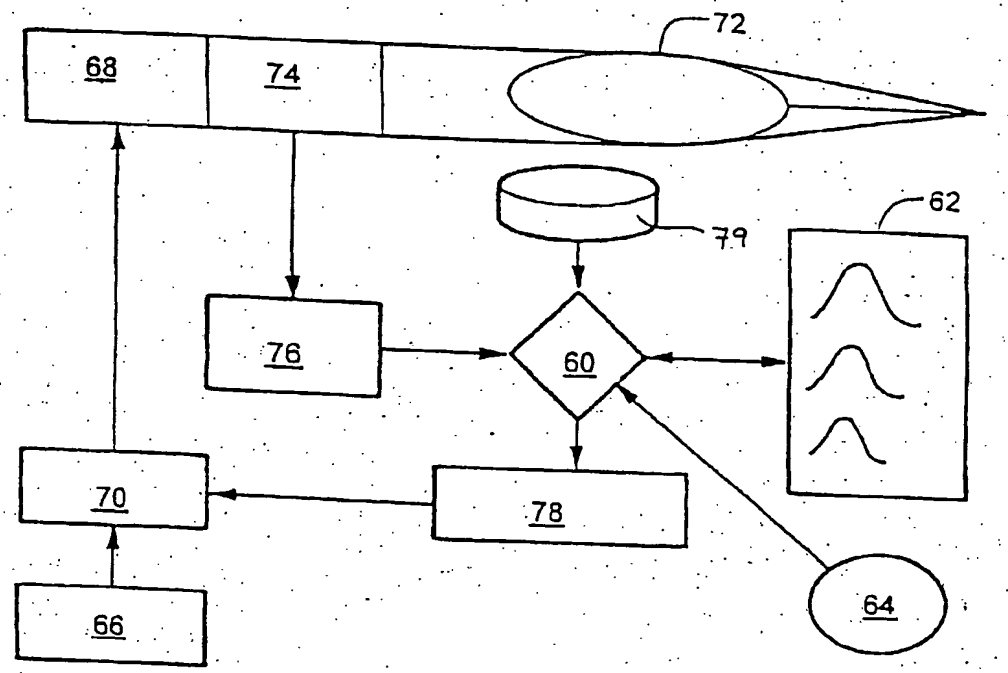

Fig. 3

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Fig. 4

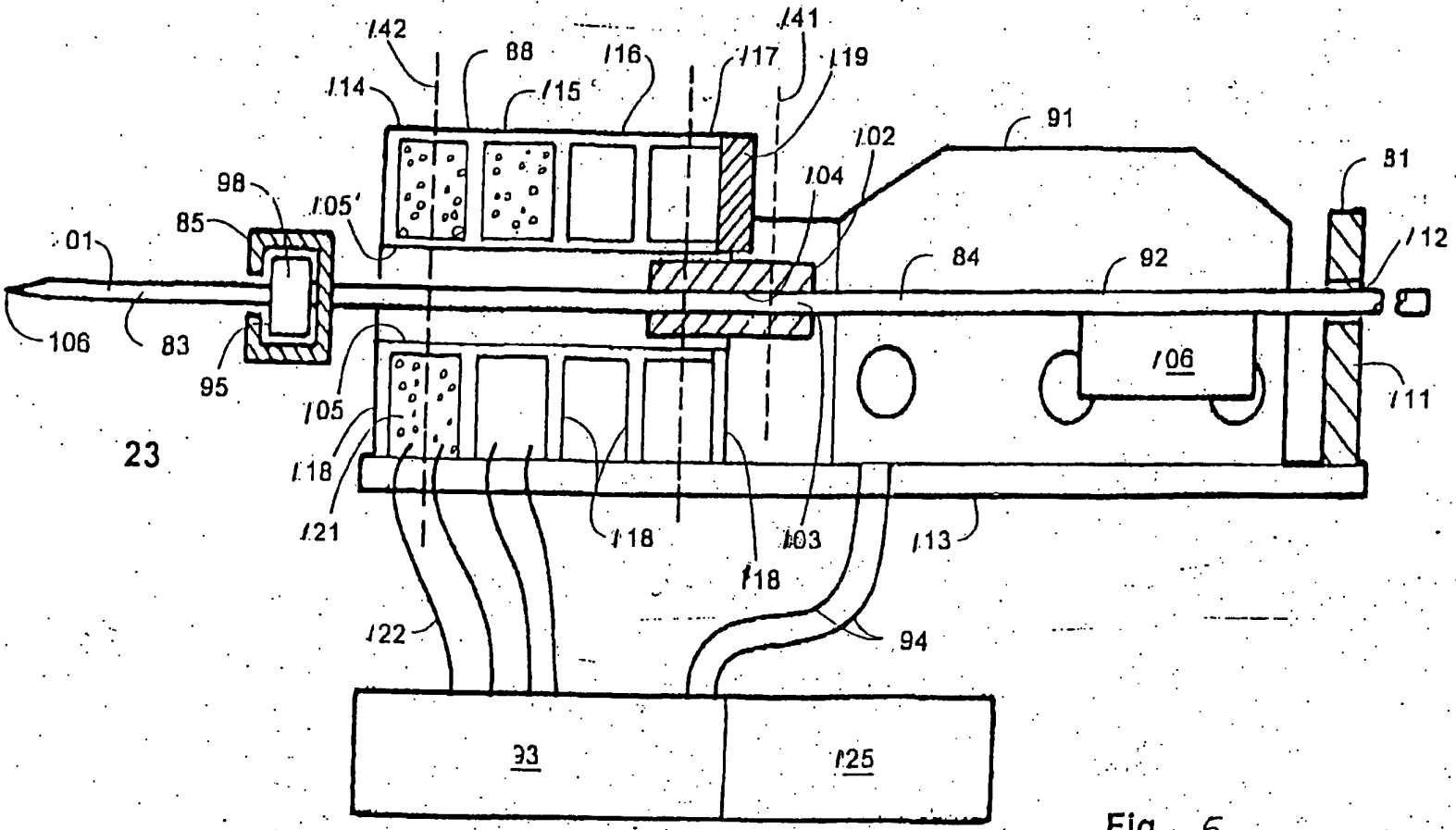

Fig. 5

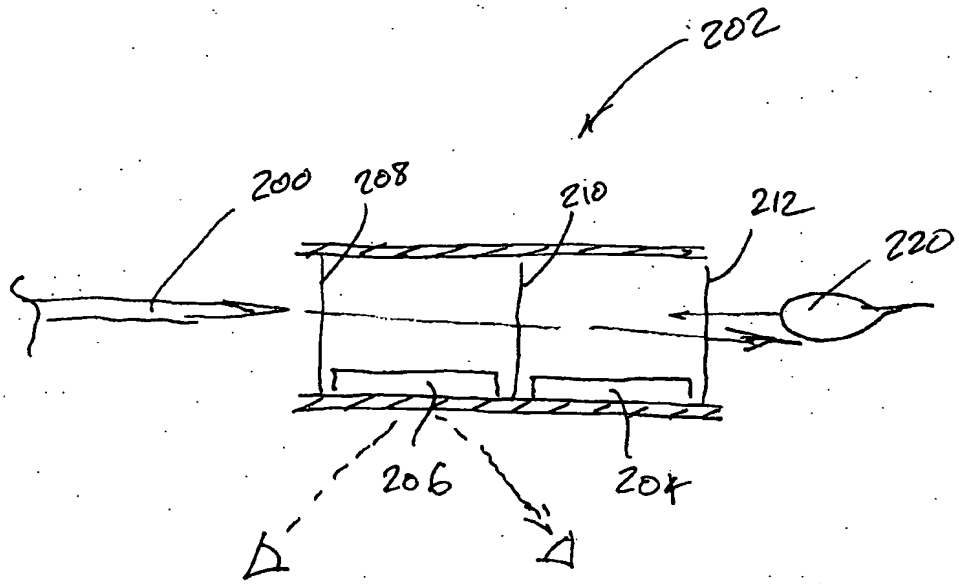

FIG_6